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| APPLICATION NO.                                                                                                                           | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.        | CONFIRMATION NO.       |
|-------------------------------------------------------------------------------------------------------------------------------------------|-------------|----------------------|----------------------------|------------------------|
| 10/797,303                                                                                                                                | 03/09/2004  | Gary Weller          | 514362001410               | 4452                   |
| 7590                                                                                                                                      | 06/23/2009  |                      |                            |                        |
| John S. Nagy<br>(Fulwider, Patton , Lee & Utecht, LLP)<br>Howard Hughes Center<br>6060 Center Drive, Tenth Floor<br>Los Angeles, CA 90045 |             |                      | EXAMINER<br>YABUT, DIANE D |                        |
|                                                                                                                                           |             |                      | ART UNIT<br>3734           | PAPER NUMBER           |
|                                                                                                                                           |             |                      | MAIL DATE<br>06/23/2009    | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/797,303             | WELLER ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | DIANE YABUT            | 3734                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 10 March 2009.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 29-36 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 29-36 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ .                                                        | 6) <input type="checkbox"/> Other: _____ .                        |

## DETAILED ACTION

This action is in response to applicant's amendment received on 03/10/2009.

The examiner acknowledges the amendments made to the claims.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 29-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Deem et al.** (U.S. Patent No. **6,558,400**) in view of **Adams et al.** (U.S. Pub. No. **2003/0132267**).

Claims 29-30 and 35-36: Deem et al. disclose a stapling member or cartridge assembly **170** or **190** for stapling the fold of stomach tissue comprising a cartridge assembly having a longitudinal axis, the cartridge assembly having a first tissue acquisition member and a second tissue acquisition member separated by a removable septum **184** or **196**, each tissue acquisition member including a tissue receiving cavity sized to receive a fold of stomach tissue, the tissue receiving cavities being coupled to a vacuum port **174** or **193**, and also an anvil member **182** (Figures 9A-11B, col. 10, lines 39-65, col. 11, line 3 to col. 12, line 33).

Deem et al. disclose the claimed device except for the first tissue acquisition member being pivotable about a longitudinal axis or longitudinal hinge in relation to a second tissue acquisition member.

Adams et al. disclose a stapler with opposing first **10** ("anvil member") and second ("stapler member") **17** tissue acquisition members, wherein the first tissue acquisition member is pivotable about the longitudinal axis of the stapler in relation to a second tissue acquisition member about a longitudinal hinge **61** (Figures 21-25, paragraph 125). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a pivotable first tissue acquisition member, as taught by Adams et al., to Deem et al. in order to accommodate variably-sized tissue sections and since it was known in the art that pivotable tissue acquisition members facilitate grasping and apposition of tissue to ensure engagement of tissue in stapling devices.

Claims 31-32: Deem et al. disclose an expandable element **52** being selected from the group consisting of a scope, a balloon, and a wire form, and the device being adapted for use with an endoscope (Figures 3A-3C and 17A, col. 8, lines 31-39, col. 15, lines 40-44).

Claims 33-34: Deem et al. disclose the claimed device except for the septum being made of a bioabsorbable material selected from the group consisting of polylactic acid (PLA), poly(lactic-co-glycolic acid) (PLGA), and polyglycolic acid (PGA). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a septum made of some bioabsorbable material since it has been held to be within the

general skill of a worker in the art to select a known material on the basis of its suitability for the intended use.

***Response to Arguments***

3. Applicant's arguments filed 03/10/2009 have been fully considered but they are not persuasive.

4. The applicant generally argues that there is no apparent benefit for modifying Deem with Adams since the staple housing of Deem would have to made wider, taller, and more complex and that "variably-sized" stomach wall tissue is not cited in either reference as a problem. The examiner disagrees. As maintained above, the benefit of having the tissue acquisition member of Deem being pivotable along a longitudinal hinge, as taught by Adams, would be allowing the member to accommodate variably-sized tissue sections" which is well known in the art of stapling devices.

5. Applicant also argues that Adams does not teach tissue acquisition members **10** and **17**, but rather teaches a grasping device **108** (paragraph 68). However, this refers to a first embodiment of the invention and the examiner refers to a seventh embodiment of the invention (Figures 21-25), wherein Adams does in fact point to anvil member **10** and stapler member **17** having tissue receiving capabilities (paragraph 125).

***Conclusion***

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/  
Examiner, Art Unit 3734

/Todd E Manahan/  
Supervisory Patent Examiner, Art Unit 3734